

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

evaluation of the effectiveness of shock wave therapy in drag-resistant impotence

Protocol summary

Study aim

Evaluation of effectiveness of shock wave therapy in patients with erectile dysfunction

Design

Clinical trial without control group, without parallel group, without randomization on 50 patients.the outcome assessment was blinded.

Settings and conduct

Patients will be recruited from the urology outpatient clinic of Emam Reza hospital.After providing a detailed explanation of the study aims and obtaining informed consent, eligible participants will be enrolled. The intervention will consist of one session per week of shockwave therapy for 6 weeks, with an energy flux density of 0.25 millijoules per square millimeter. Participants will then be followed up at 3 months post-treatment. The international index of erectile function (IIEF) questionnaire will be used to assess treatment response and evaluate changes in erectile function.

Participants/Inclusion and exclusion criteria

Inclusion criteria:All patients who dont be treated with maximum dose of PDEi drugs for 4 times Exclusion criteria: Lack of consent to participate in the study and the presence of contraindications for performing shockwave therapy such as hemodynamic disturbances

Intervention groups

All patients with erectile dysfunction who dont be treated with PDEi drugs

Main outcome variables

1- improve orgasmic performance 2- improve libido 3- improve erectile function 4- improve sexual satisfaction 5- overall satisfaction of the individual

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230125057230N1**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-09, 1402/05/18**

Update count: **0**

Registration date

2023-08-09, 1402/05/18

Registrant information

Name

aida jamlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2809

Email address

aidajamlou@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-13, 1401/12/22

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of the effectiveness of shock wave therapy in drag-resistant impotence

Public title

evaluation of the treatment method of nephrolithiasis with with shock wave in infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all patient with erectile dysfunction who dont be treated with PDEi drugs

Exclusion criteria:

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **31**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

during this study, for 6 weeks and every week a session of shockwave therapy with 0.25mJ/mm2 energy was performed for patients and follow up three months later

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی تبریز

Street address

no.13.dr hesabi square.shahgoli.tabriz.iran

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tabriz

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Postal code

۵۱۶۶۸۱۱۷۰۷

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TBZMED.REC.1402.102

Health conditions studied

1

Description of health condition studied

erectile dysfunction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

erection

Timepoint

at the beginning of study and 3 months after shockwave therapy

Method of measurement

IIEF questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with erectile dysfunction that can't have appropriate erection after receiving maximum dose of PDE5i drugs for 4 times

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

urology clinic of Emma reza hospital

Full name of responsible person

faraji

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

aida jamlou

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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assistant professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available